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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,736	06/18/2001	Michael Glotzer	0652.2260001/EKS/AES	8755
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STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005				
			EXAMINER LI, RUIXIANG	
			ART UNIT 1646	PAPER NUMBER

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/881,736

Applicant(s)

GLOTZER ET AL.

Examiner

Ruixiang Li

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 12 and 45-77 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 12 and 74-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45, 46, 51-66 and 68-73 is/are rejected.
- 7) ☒ Claim(s) 47-50 and 67 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/15/2004.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

I. Status of Application, Amendments, and/or Claims

The Request filed on December 15, 2004 for Continued Examination (RCE) under 37 CFR 1.114 of Application 09/881,736 is granted. An action on the RCE follows.

The amendment filed on December 15, 2004 has been entered in full. Claims 11 and 13-44 are canceled. Claims 45-77 are added. Claims 1-6, 12, and 45-77 are pending. Claims 45-73 are under consideration. Claims 74-77 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention (Invention group II as set forth in Paper No. 10, mailed on 04/17/2003).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

II. Withdrawn Objections and/or Rejections

Applicants' cancellation of claims 13-33 has made all the rejections and objections set forth in the previous office action (Paper No. 06022004, mailed on 06/15/2004) moot.

III. Information Disclosure Statement

The information disclosure statement filed on 12/15/2004 has been considered by the Examiner and a signed copy of the substitute form PTO-1449 is attached to the office action.

IV. Claim Rejections Under 35 U. S. C. § 112, 1st Paragraph

(i). The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(ii). Claims 45, 46, 51-57, 61-66, and 68-73 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying a compound having the potential to inhibit cytokinesis employing a CYK-4 protein set forth in SEQ ID NO: 2, 4, or 6 does not reasonably provide enablement for a method for identifying a compound having the potential to inhibit cytokinesis employing any other CYK-4 proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

The claims are drawn to a method for identifying a compound having the potential to inhibit cytokinesis by determining the compound's ability to inhibit the CYK-4 stimulated GTP hydrolysis by a Rho family GTPase, to inhibit the binding of CYK-4 protein to members of MKLP1 subfamily, or to inhibit self association of CYK-

4 proteins. Thus, the claims are broad and encompass a screening method employing any CYK-4 proteins and its fragments. However, other than the three CYK-4 proteins, a human CYK-4 protein of SEQ ID NO: 2, a murine CYK-4 of SEQ ID NO: 4, and a *C. elegans* CYK-4 protein of SEQ ID NO: 6, the specification fails to provide sufficient guidance and working example to isolate and identify additional CYK-4 proteins. The prior art at the time when the instant application was filed does not teach additional CYK-4 proteins that play critical roles in cytokinesis. In order to practice the claimed methods, one of skilled in the art would have to isolate and characterize additional CYK-4 proteins first. Thus, it would take undue experimentation for one skilled in the art to make and use the claimed method.

Accordingly, the instant disclosure fails to enable the screening methods employing CYK-4 proteins other than the CYK-4 proteins set forth in SEQ ID NOS: 2, 4, and 6. It would require undue experimentation for one skilled in the art to make and use the claimed invention.

V. Claim Rejections under 35 USC § 112, 2nd paragraph

New claims 45, 46, 51-64, 68-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i). New claims 56 and 57 are indefinite because the sequences of MKLP1 proteins are referred to a commercial database and such a database is subject to change and correction. It is suggested that a sequence identifier (instead of the database accession number) be inserted after each term to overcome this rejection.

(ii). New claims 45, 46, 51-64, and 70-73 are indefinite because they recite acronyms "CYK-4" and "MKLP1". Such a term is determined arbitrarily without a definitive structure. Others in the field may isolate the same protein and give an entirely different name. Thus, use of a particular name given to the protein by various workers in the field fails to distinctly claim what the protein is. Applicants should particularly point out and distinctly indicate a protein by a sequence identifier and/or by spelling out the terms (for example, adding a limitation, "wherein said CYK-4 protein has the amino acid sequence of SEQ ID NO: 2" or "wherein said CYK-4 protein is selected from the group consists of human CYK-4 of SEQ ID NO: 2 and murine CYK-4 of SEQ ID NO: 4).

Applicants argue that the acronyms "CYK-4" and "MKLP1" do not render the claims indefinite because one of ordinary skill in the art could interpret the metes and bounds of the claims reciting these terms. Applicants submit that "CYK-4" refers to a protein represented by the CYK-4 protein encoded by the *C. elegans* *cyk4* gene, which derives its name from the *C. elegans* *cyk-4* locus and sequences for the human and mouse CYK-4 proteins are provided in the specification as SEQ ID NOS: 2 and 4. Applicants further submit that "MKLP1" represents human mitotic kinesin-like protein 1. This is not found to be persuasive because both acronyms are not defined to refer a specific structure in the specification, rendering the claims indefinite for the reasons noted above. If the term "CYK-4" is intended to refer to the proteins of SEQ ID NOS: 2 and 4, it should be clearly indicated so in each independent claim to overcome the rejection. In addition, MKLP1 should be spelled out in each independent claim.

(iii). New claims 60, 68, and 69 are indefinite because they recite "amino acid residues 1-120". It is unclear which amino acids 1-120 are referred by the limitation. It is

suggested that a sequence identifier be added (for example, "amino acid residues 1-120 of SEQ ID NO: 2") to overcome the rejection.

(iv). Claim 54 is indefinite because it recites in the preamble and at the end of the claim recites the word "interfere". From the specification, it is clear that only a compound that inhibits the function of CYK-4 protein has the potential to inhibit cytokinesis. However, "interfere" literally means either enhance or inhibit. It is suggested that the word "interfere" be replaced by "inhibit" to overcome the rejection. Claims 55-63 are rejected as dependent claims from claim 54.

VI. Claim Objections

(i) Claims 48-50 and 67 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

(ii). Claims 45-47, 51-58, and 60-73 are objected to because they recite non-elected subject matter (murine CYK-4 of SEQ ID NO: 4). On Applicant's request, the Examiner clarifies that the restriction requirement set forth in Paper No. 10 mailed on 4/17/2003 intended to set forth additional invention groups between human CYK-4 of SEQ ID NO: 2 and murine CYK-4 of SEQ ID NO: 4, as indicated in Paper No. 06022004 (mailed on 06/15/2004). However, in view of applicants' argument about the generic linking claim practice, the Examiner agrees to examine all the generic linking claims, and to search and examine murine of SEQ ID NO: 4 if a generic claim is allowable.

VII. Conclusion

No claims are allowed.

VIII. Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li

Ruixiang Li, Ph.D.
Examiner
February 18, 2005